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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 4082004

Application Number: 09/772,520
Filing Date: January 29, 2001
Appellant(s): GARING, FRANCIS L.

Robert Hanson
For Appellant

EXAMINER'S ANSWER

This is in response to the Appeal Brief filed 23 December 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is substantially correct. The changes are as follows:

Claims 1-3 and 5-31 are pending. Claims 1, 2, 5, 7-10, 12, 13, and 21-23 are allowed. Claims 3, 6, 11, 14-20, and 24-31 remain rejected and stand appealed. Claim 4 has been cancelled in an Amendment under 37 CFR 1.116 submitted by Appellant on 30 June 2003, which accompanied a first Appeal Brief. In the supplemental Appeal Brief (filed 23 December 2003, to which the instant Examiner's Answer is written), Appellant indicated that the status of the Amendment was not indicated in the Office action mailed 23 September 2003 and is currently unknown (Appeal Brief, paragraph bridging pages 2-3). The Office action mailed 23 September 2003 indicated that claim 4 was still pending because Appellant did not expressly request the cancellation of claim 4 (page 2, item 1). However, this was in error. An Amendment under 37 CFR 1.116 was in fact filed on June 30, 2003 that directed the cancellation of claim 4. The amendment was entered and claim 4 was cancelled.

Claims 3, 6, 11, 14-20, and 27-30 remain rejected under 35 U.S.C. 112, 2nd paragraph. The rejection is withdrawn from claims 2 and 22-25.

Claims 6, 11, and 24-31 remain rejected under 35 U.S.C. 112, 1st paragraph, as not being supported by an adequate written description. The rejection is withdrawn from claims 2-4.

Claims 27-30 remain rejected under 35 U.S.C. 112, 1st paragraph, for lack of enablement.

Claim 26 was objected to in the Office action mailed 23 September 2003, as being in improper dependent form for failing to further limit the subject matter of a previous claim. Appellant did not address this objection.

(4) Status of Amendments After Final

The Appellant's statement of the status of amendments contained in the brief is correct- an Amendment under 37 CFR 1.116 was filed with the first Appeal Brief on June 30, 2003. Appellant indicates that the status of the Amendment is unknown (Appeal Brief, page 3, 1st full paragraph). As discussed above, the Amendment under 37 CFR 1.116 filed on June 30, 2003 has been entered and claim 4 was cancelled.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The Appellant's statement of the issues in the brief is substantially correct. The differences are, that the rejections of claims 2 and 22-25 under 35 U.S.C. 112, 2nd paragraph, and claims 2-4 under 35 U.S.C. 112, 1st paragraph, have been withdrawn.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 2, 3, 6, 11, 14-20, and 24-31 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 3, 6, 11, 14-20, and 27-30 on appeal stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3: the recitation, "further defined as an essentially homogeneous population of seed" renders the claim indefinite. Claim 2 reads, "A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228." Claim 3 is directed to "The population of seed of claim 2, further defined as an essentially homogeneous population of seed." The "further defined as" recitation in claim 3 renders the claim indefinite because it is unclear what affect this recitation has on the

scope of the claim. The recitation, "A population of seed of the corn variety I026458" in claim 2 indicates that the population of claim 2 is a homogeneous population of seed of corn variety I026458. The recitation, "essentially homogeneous," in claim 3 would thus appear to be superfluous. However, reading the claims in light of the specification, lines 17-22 of page 5 indicate that inbred seed can form less than 100% of an essentially homogeneous population. Thus, the scope of claim 3 is unclear. Note that if claim 3 were amended to read, "An essentially homogeneous population of corn seeds consisting essentially of the seed of claim 1", the claim would have a definite meaning.

Appellant's argument and Examiner's response:

Appellant argues that while claim 2 is directed to a population of seed of corn variety I026458, it is not necessary that the population be essentially homogeneous. Appellant provides the definition for "population" from the Merriam-Webster on-line dictionary (Exhibit A), and argues that the relevant definition is "a body of persons or individuals having a quality or characteristic in common." Appellant also provides the definition for "homogeneous" (Exhibit B), which is "of uniform structure or composition throughout," and argues that a population of seed of corn variety I026458 could be non-uniform in size or shape, yet have the common quality of being a corn plant of variety I026458. Appellant argues that as such, claim 3 is in proper dependent form and is not indefinite. (Appeal Brief, paragraph bridging pages 6-7).

Appellant appears to be arguing that the recitation, "essentially homogeneous," in claim 3 indicates that the individual I026458 seeds of the claimed population share a uniform structure, for example size and shape. However, the issue does not concern the size and shape of individual seeds. Further, Appellant's argument is inconsistent with the discussion of

"essentially homogeneous population of inbred seed" in the specification. Page 5, lines 15-21, of the specification states, "Essentially homogeneous populations of inbred seed are those that consist essentially of the particular inbred seed, and are generally free from substantial numbers of other seed, so that the inbred seed forms between about 90% and about 100% of the total seed, and preferably, between about 95% and about 100% of the total seed. Most preferably, an essentially homogeneous population of inbred corn seed will contain between about 98.5%, 99%, 99.5% and about 99.9% of inbred seed, as measured by seed grow outs." This definition does not concern the size and shape of the particular inbred seed of an essentially homogeneous population of inbred seed, but rather addresses the percentage of the population that is made up of the particular inbred seed versus other varieties of seed. The scope of claim 3 is unclear because the essentially homogeneous population of that claim can comprise varieties of seed other than I026458, whereas the population of claim 2 is directed to a single variety of seed, that of corn variety I026458. Appellant's argument also indicates that the members of the population of claim 2 have the common quality of being a corn plant of variety I026458. As noted above, amending claim 3 to read "An essentially homogeneous population of corn seeds consisting essentially of the seed of claim 1", would obviate this rejection.

In claim 14: the recitation "An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458" in lines 1-2 renders the claim indefinite. The I026458 seed can only produce I026458 plants. The claim does not mention any other type of seed. The population can therefore only consist of I026458 plants. It is then not clear why the population is referred to as "essentially homogeneous," since such populations can

comprise more than one variety of plant. Amending claim 7 to read, "An essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of corn plant I026458, a sample of said seed having been deposited under ATCC Accession No. PTA-3228" would obviate the rejection.

Appellant's argument and Examiner's response:

Appellant argues that a population need not be essentially homogeneous (Appeal Brief, paragraph bridging pages 7-8). However, the claim clearly states, "An essentially homogeneous population of corn plants..."

Appellant again argues that a population of plants grown from I026458 seed could vary in size or other characteristics due to environmental or other conditions, but still be population produced by growing I026458 seed (Appeal Brief, paragraph bridging pages 7-8).

However, again, Appellant's interpretation of "essentially homogeneous population" differs from that provided on page 5, lines 15-21 of the specification, which explains how other varieties of seed may be in an essentially homogeneous population of a particular variety of seed. It is rather well known in the art, when referring to plants, that the term "variety" is used to distinguish genetically distinct taxonomic groups below the species level. I026458 is a variety of corn plant. Corn plant "X" is another variety of corn plant, and is genetically distinct from variety I026458. I026458 seed cannot produce "X" corn plants, but can only produce I026458 corn plants. It is not at all clear why Appellant is arguing that an "essentially homogenous population of corn plants" refers to the non-uniform nature of the same variety of corn plant, when the definition in the specification (page 5, lines 17-20) concerns the amounts of genetically different varieties of corn that can be in an essentially homogeneous population. Claim 14

indicates that growing only the seed of the inbred corn plant I026458 produces the corn plants of the essentially homogeneous population of corn plants. But if only one variety of seed is being grown, only one variety of corn plant can be produced. It therefore remains unclear why claim 14 is directed to an essentially homogeneous population of corn plants that, according to the specification, can comprise more than one variety of plant. If the population of claim 14 is to encompass only plants produced by growing I026458 seeds, as Appellant appears to be arguing, it is not clear why the claim is directed to an essentially homogeneous population of corn plants. The definition on page 5 of the specification also indicates that an essentially homogenous population of an inbred corn seed may be comprised of 100% of that seed. However, limitations of the specification cannot be read into the claims. As noted above, amending claim 14 to read, "An essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of corn plant I026458, a sample of said seed having been deposited under ATCC Accession No. PTA-3228" would obviate this rejection.

The rejection of claim 2, regarding the recitation, "population of seed of the corn variety I026458" is withdrawn, upon further consideration of Appellant's arguments. It is also noted that Appellant indicates that a population of seed of corn variety I026458 have the common quality of being a corn plant of variety I026458 (Appeal Brief, paragraph bridging pages 6-7).

In claims 6 and 11: the recitation, "in accordance with" renders the claims indefinite. The meaning of this recitation is not exactly clear, and makes the metes and bounds of the claims unclear.

Appellant's Arguments and Examiner's Response:

Appellant provides the definition for "accordance" that appears in the on-line version of the Merriam-Webster Dictionary, one of which is "agreement, conformity" (Exhibit C). Appellant argues that the term therefore has a well known meaning in the art and its use in the claim is not indefinite (Appeal Brief, page 8, 2nd full paragraph).

It remains unclear whether the claimed inbred plant cell or plant has the SSR profile or the isozyme typing profile of Tables 6 and 7, respectively. It is not clear, for example, what is meant by an SSR profile that is in conformity with the profile shown in Table 6. Is the SSR profile the same, or is it not the same, as that shown in Table 6? Would an SSR profile that generally follows the trend of the profile of Table 6, but which differs at one or a few loci, be considered in "conformity" or "in accordance" with the profile of Table 6? It is not clear what is meant by a marker profile that "agrees" with another marker profile. Are they the same or not? If the profiles are not exactly the same, then it is not clear what the differences are. If Appellants intend for the claimed inbred plant cell or plant to have the same profiles as those shown in Tables 6 and 7 for corn plant I026458, it is suggested that part (a) of claims 6 and 11 be replaced with --the SSR profile for corn plant I026458 shown in Table 6; and--, and that part (b) of the claims be replaced with --the isozyme typing profile for corn plant I026458 shown in Table 7--.

In claims 15, 17, and 20: the recitation "capable of expressing" in line 1 of claim 15 and line 2 of claims 17 and 20 renders the claims indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation in claim 15 be replaced with --having--, and in claim 20 with --has--.

Similarly, the recitation "is capable of regenerating" in line 2 of claim 17 renders it indefinite. It is suggested that the recitation "the tissue is capable of regenerating plants capable of expressing" be replaced with --plants, when regenerated from said tissue culture, have--.

Appellant's Argument and Examiner's Response:

Appellant argues that the term "capable" is well known in the art and is thus fully definite, and that claim breadth is not indefinite. Appellant argues that one of skill in the art would understand whether a corn plant is capable of expressing all of the traits of corn plant I026458 by way of its biological deposit, and one would therefore ascertain whether a plant is capable of expressing all of the traits of I026458 based on direct comparisons (Appeal Brief, page 10, 1st full paragraph).

However, it is maintained that the recitation, "capable of expressing", renders the claim indefinite because the recitation can be interpreted to indicate that, while the plant has the capacity to express the characteristics, for some reason it may not. Certain characteristics of a plant are expressed only at certain times of its life cycle, and are incapable of being expressed at other times. The colors of flower parts such as silks, or fruit parts such as husks, are examples. The promoters of many genes conferring traits require a transcription factor to become active. Is a plant that has such a gene, but not the transcription factor, considered "capable of expressing" that gene, and the trait associated with that gene, and is such a plant encompassed by the claims? Furthermore, traits such as plant height or yield are environmentally influenced. A particular value for plant height or seed yield observed in Appellant's tested growing environment might not be observed in another environment. The claim amendments suggested above particularly point out that the plant does have all of the morphological and physiological characteristics of

I026458, while not requiring all of the characteristics to be expressed at all times of the plant's life cycle.

In claims 16 and 27: the claims appear to broaden the scope of the claims from which they depend, or raise doubts as to whether the corn plant of claim 16 must be male sterile and whether the corn plant of claim 27 has the traits of the corn plant of parent claim 5. Claims 16 and 27 add on a gene or locus to the genome of the plant of their parent claims. The specification does not define the plants expressing all the morphological and physiological characteristics of I026458 as being male sterile; in fact, the plant of claim 15 (from which claim 16 depends) is male fertile. Thus claim 16 cannot incorporate all the limitations of claim 15 because it is directed to a plant that is not male fertile. Claim 27 is indefinite for the same reasons as for claim 16- it is not clear if the plant of claim 27 has all of the characteristics of the plant of parent claim 5. There is no indication as to how the plants acquired the genes, and the plant of their parent claims does not possess the gene or locus. It is suggested that claim 16 be amended to recite that the plant was produced from the plant of claim 15, and to indicate how the cytoplasmic or nuclear gene conferring male sterility was introduced into the plant of claim 15. Claim 27 should be similarly amended.

Appellant's argument and Examiner's response:

Appellant argues that claim 16 adds a gene conferring male sterility, while claim 27 adds a single locus conversion, to the parent claim. Appellant argues that the claims contain a reference to the parent claim, contain a further limitation of the subject matter claimed in the main claim, and incorporate all elements of the claim from which they depend. Appellant argues

that how the plants acquire the added elements is irrelevant to the scope or definiteness of the claims, as they are product claims, not process or product by process claims (Appeal Brief, paragraph bridging pages 9-10).

However, the claims do not incorporate all elements of their parent claims. The plant of claim 15 is male fertile. The plant of claim 16, however, is not male fertile. Therefore, claim 16 does not incorporate all elements of the claim from which it depends. Further, as the plant of claim 15 is male fertile, it is contradictory to say that claim 16 incorporates all elements of claim 15, yet is directed to a plant that is not male fertile. The single locus conversion of the plant of claim 27 does not have to be a gene that confers male sterility. However, as the locus may encode any trait, and can affect the plant of parent claim 5 in any manner, the plant of claim 27 does not have to have all of the traits expressed by the plant of claim 5. The plant of claim 27 then would not have all of the limitations of the plant of claim 5. Claim amendments are suggested at the end of this Examiner's Answer, in Appendix A.

The rejection of claim 18, in regards to the recitation, "derived from", is withdrawn, upon further consideration of Appellant's arguments. However, note that claim 18 remains rejected because it is dependent on claim 17.

The rejection of claim 19, in regards to the recitation, "the regenerable cells comprise protoplasts", is withdrawn, upon further consideration of Appellant's arguments. However, note that claim 18 remains rejected because it is dependent on claim 17.

The rejection of claim 22, for reciting a new process different from its parent claim, is withdrawn upon further consideration of Appellant's arguments.

In claim 28: the article "a" in the recitation "wherein the single locus was stably inserted into *a* corn genome" (emphasis added) renders the claim indefinite. The recitation does not make clear if the genome is that of I026458 or that of a different corn plant.

Appellant's Arguments and Examiner's Response:

Appellant notes that the single locus may or may not have been directly inserted into the genome of the claimed plant, and argues that this does not render the claim indefinite, because the single locus may have been inserted into a parent I026458 plant and self pollinated to produce the claimed plant. Appellant argues that the single locus need not have been directly inserted into the genome of I026458, and that loci that are stably inserted into a corn genome are also stably inherited (Appeal Brief, page 11, last paragraph).

However, a parent plant of inbred variety I026458 is itself I026458. Therefore it remains unclear, what other genomes are encompassed by "a corn genome", and how does it relate to the plant of claim 28? Further, if the single locus is transformed into an entirely unrelated plant and introduced into I026458 by crossing and selection, the resultant plant would have the single locus but it would not otherwise be exactly the same as I026458.

In claim 30: the recitations, "yield enhancement," "improved nutritional quality," and enhanced yield stability" are relative terms that have no definite meaning, and make the metes and bounds of the claim unclear.

Appellant's argument and Examiner's response:

Appellant argues that those of skill in the art understand all the terms and there is no prohibition upon the use of relative terms. Appellant argues that the terms must be read in the context of the claim in which they are found, that the subject claim recites a single locus that confers the traits of yield enhancement, improved nutritional quality, and enhanced yield stability, and that it is understood that the enhancement of yield or yield stability and improvement in nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim would thus be fully understood by one of skill in the art (Appeal Brief, page 12, 1st full paragraph).

However, relative terms cannot be used if the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Here, the specification does not provide any such standard. What one may consider an enhancement or improvement over a plant lacking the single locus, may not be considered so by another, in the absence of a defined standard that must be met. Further, what nutritional qualities are contemplated, and how are they improved?

Claims 6, 11, and 24-31 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is withdrawn from claims 2, 3, and 14 upon further consideration of Appellant's arguments. Claim 4 is cancelled.

The claims are broadly drawn towards a corn plant, or a cell thereof, wherein the plant is produced by growing seed of corn variety I026458, wherein the corn plant has an SSR profile or an isozyme typing profile that is in accordance with any of the profiles, for three different plants, shown in Tables 6and 7 respectively; any hybrid corn seed produced by crossing corn plant I026458 with any second, distinct inbred corn plant; any hybrid corn plant produced by growing said hybrid seed; inbred corn plant I026458 further comprising any single locus conversion; a method of producing any inbred corn plant derived from corn variety I026458 comprising crossing I026458 plants with any second corn plant, and crossing the progeny with itself or any other plant to produce further progeny.

The specification describes numerous morphological and physiological characteristics, and provides the names of SSR markers and isozyme loci, of inbred corn plant I026458 (page 24, lines 2-5; Tables 1 and 2, pages 24-26; page 26, line 10 to page 27, line 16; Table 3, pages 28-29; Table 6, pages 62-64; Table 7, page 65). The specification indicates that a deposit of 2500 seeds of I026458 has been made with the American Type Culture Collection, under the Accession No. PTA-3228, under the terms of the Budapest Treaty (amendment to page 29, lines 8-15, of the specification, in the paper received 18 November 2002, page 3). It is noted that all restrictions to the availability of the public to the deposited seed will be irrevocably removed upon the granting of a patent (Declaration of Biological Culture Deposit, submitted with the papers received 18 November 2002). The specification also describes morphological traits, names of SSR markers and isozyme loci, of a single hybrid corn plant, designated "7041221," produced by crossing I026458 with an inbred corn plant designated "01IUL6" (page 54, lines 1-6; Table 4, page 57; Table 5, pages 58-59; Table 8, pages 66-67; Table 9, page 68).

A review of the full content of the specification indicates that seed of inbred corn plant I026458, and hybrid seed produced by crossing an I026458 plant with any other corn plant, are essential to the operation and function of the claimed invention. A search of seed of inbred corn plant I026458 indicates that it is novel and unobvious.

A review of the language of claims 24-26 indicates that the claims are drawn to a genus, i.e., any and all hybrid corn seeds, and the hybrid corn plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing inbred corn plant I026458 with any second, distinct inbred corn plant. Variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-I026458 parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-I026458 inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ.

The specification does not describe any hybrid corn plants produced by crossing I026458 with any other inbred corn plant, except for the hybrid designated "7041221" (page 54, lines 1-6; page 56, line 12 to page 59, line 4). The descriptions of I026458 and 7041221, however, do not provide any information concerning the description of all other hybrids. There is no evidence on the record of any relationship between the structure of the complete genome of hybrid 7041221 and the complete genome of other hybrids. Hybrids produced by crossing I026458 with other, distinct inbred corn plants would, of course, produce plants that do not express the same traits as I026458, and hybrids produced by crossing I026458 with distinct inbred corn plants other than 01UL6 also would not express the same traits as 7041221. The descriptions of I026458 and

7041221 do not provide any information concerning the morphological and physiological characteristics of other plants. In view of these considerations, a person of skill in the art would not have viewed the teachings of the specification as sufficient to show that the Applicant was in possession of the claimed genus of hybrid seeds and plants produced therefrom.

The specification also indicates that Table 6 provides names of loci where the SSR markers supposedly reside, for three different corn plants, and a numerical value for each marker that represents numbers of base pairs (specification, page 61, line 5 to page 62, line 9). The specification indicates on page 61, lines 19-20, that the SSR analyses were conducted at Celera AgGen, and on page 64, following Table 6, that primers used in the analyses were also from Celera AgGen.

Claims 6 and 11 are drawn to an inbred corn plant, or a cell thereof, wherein the plant is produced by growing a seed of inbred corn variety I026458, said plant or cell thereof comprising an SSR genetic marker profile in accordance with the profile shown in Table 6, or a isozyme typing profile in accordance with the profile shown in Table 7.

However, while names and numbers of base pairs of loci of the SSR markers are provided, the actual nucleotide sequences that make up the markers are not provided. Names of loci alone do not describe the structures of the markers themselves. Without a description of the sequences of the markers, one cannot confirm their presence. Table 7 provides names of loci where isozyme markers reside, for three different corn plants, and a numerical value that represents the numbers of alleles at isozyme loci types. The nucleotide sequences that make up these loci are not described.

The specification also indicates that single locus converted plants are defined as plants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus). The specification contemplates numerous different single loci involved in expressing various traits (pages 30-35). The specification provides the origin and breeding history of a single exemplary single locus converted plant, in which the trait of cytoplasmic male sterility was introduced not into corn plant I026458, but into another corn inbred (pages 35-36).

Claims 27-30 are drawn towards I026458 plants further comprising a single locus conversion, or wherein the single locus was stably inserted into a corn genome by transformation. A review of claims 27-30 indicate that they encompass a genus of corn plants, each species of which can differ in the morphological and physiological traits that they can express, since they would comprise different single locus conversions. Claims 27-30 also do not place any limitation on the trait conferred or affected by the single locus conversion. However, the specification does not describe identified or isolated single loci for all corn plant traits. While the specification, on pages 31-35, recites traits that are contemplated to be introduced into I026458, single loci governing all of these traits have not been identified. For example, single loci that govern yield enhancement or enhanced yield stability, recited in claim 30, are not described. Claims 27-30 also broadly encompass single loci that have not been discovered or isolated. A single locus governing "industrial usage" (recited in the specification on page 31,

line 21), for example, is not known in the art. Further, a locus, for example one that encodes a transcription factor, can affect more than just one gene, and multiple traits. Such plants would express different morphological and physiological traits from I026458, which are not described.

The specification also indicates that the present invention provides a method of producing an inbred corn plant derived from corn plant I026458. The method comprises (a) crossing a I026458 plant with a second corn plant to produce a progeny plant, (b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation, (c) crossing the plant produced by growing that seed with itself or a second plant, and repeating steps (b) and (c) for an additional 3-10 generations (page 10, line 18 to page 11, line 4; page 49, line 20 to page 53, line 8).

Claim 31 is drawn to a method of producing an inbred corn plant derived from corn plant I026458. The method comprises (a) crossing a I026458 plant with a second corn plant to produce a progeny plant, (b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation, (c) crossing the plant produced by growing that seed with itself or a second plant, and repeating steps (b) and (c) for an additional 3-10 generations. A review of the claim indicates that hybrid progeny of corn plant I026458 are required to perform further crosses, and that progeny of subsequent generations can be further outcrossed with different corn plants. The hybrid progeny of corn plant I026458, and progeny plants of subsequent generations, are essential to operate the claimed method. Substantial variation is expected among the progeny plants, as the identities of the second corn plant to which I026458 may be crossed and to which progeny plants may be crossed, are not limited.

The specification teaches a single hybrid progeny corn plant, designated 7041221, produced by crossing inbred corn plant I026458 with inbred corn plant 01IUL6 (page 54, lines 3-6. However, the specification does not describe any other hybrid corn plant, or any progeny corn plants of subsequent generations, as discussed above. Hybrid plant 7041221 is not representative of all other hybrid progeny corn plants, as other hybrid progeny plants do not have both of the same parents as 7041221. Inbred produced from crossing the hybrid plants are then also not described. The Federal Register (64 Fed. Reg. 71427, 71428 (1999), Comment No. 4) indicates that a suggestion was made that the written description guidelines should distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those whose patentability rests in the steps of the process itself, and that this suggestion was adopted. Accordingly, claim 31 includes steps in which hybrids, produced by crossing inbred corn plant I026458 with a second, different corn plant, are involved in crosses. The patentability of the method of claim 31 does not lie in the method steps, which require the simple acts of crossing corn plants, allowing progeny seed to be produced, and growing progeny plants from the seed, but rather in the compositions used in the method. The method of claim 31 is not described, as the specification does not sufficiently describe the genus of hybrid plants, or any progeny of subsequent generations, for the reasons discussed above. Given the breadth of the claims encompassing all hybrid corn plants and seeds produced by crossing I026458 to any other corn plant, I026458 plants comprising any single locus conversion, and the description in the specification of only I026458 and a single hybrid, 7041221, it is submitted that the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

Appellant's Arguments and Examiner's Response:

Regarding claims 6 and 11: these claims were included in this rejection because the SSR and isozyme markers mentioned in Tables 6 and 7 are not described, for the reasons discussed above. Appellant argues that no basis has been provided for the allegation that written description for the markers in Tables 6 and 7 is lacking (Appeal Brief, page 13, 1st full paragraph). Appellant argues that the profiles are recited and the claims claim nothing more than what is provided in the tables. Appellant argues that the SSR markers were from Celera AgGen, Inc., and that isozyme markers are well known and isozyme analysis has been used for decades (Appeal Brief, page 13, 1st and 2nd full paragraphs).

Table 6 provides names of loci where the SSR markers supposedly reside, and a numerical value that represents base pairs (specification, page 61, lines 16-17). Table 7 provides names of loci where isozyme markers reside, and a numerical value that represents the numbers of alleles at isozyme loci types (specification, page 64, lines 14-15). The Office action mailed 23 September 2003 indicated that while names of loci are provided, names are not sufficient to describe the markers. Without a description of the sequences of the markers, one cannot confirm their presence. Further, claims 6 and 11 indicate that the claimed plant or cell has the SSR profile or the isozyme profile. The genome of the cells of the I026458 seed deposited with the ATCC has both the SSR profile and the isozyme typing profile shown in Tables 6 and 7 for that plant. No plant is described in the specification that has one genetic marker profile but not the other.

Appellant argues that the hybrid seeds and plants of claims 22-24 (it is assumed that Appellant is actually referring to claims 24-26) are described because they have I026458 as a parent and therefore contain a copy of the same genome as corn plant I026458, and that they have inherited half of their genetic material from I026458 (Appeal Brief, page 14, 1st full paragraph).

First, the Examiner would like to address a statement made by Appellant that may be a point of confusion. Appellant states, "All of the claimed hybrid plants having I026458 as a parent will therefore contain a copy of the same genome as corn plant I026458" (emphasis added; Appeal Brief, page 14, 1st full paragraph). This statement may be confusing, as it can be interpreted to mean that the entire genome of any of the claimed hybrids is identical to the entire genome of I026458. Since inbred corn plant I026458 must be crossed with a different corn plant to produce the claimed hybrids, the claimed hybrids cannot have entirely the same genome as I026458. It appears to the Examiner that Appellant did not intend to indicate that all of the claimed hybrid plants have entirely the same genome as I026458, as Appellant then immediately states, "That is, because I026458 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant I026458..." (emphasis added), which correctly indicates that all hybrids would inherit one-half, not all, of their genome from I026458.

The Examiner maintains that the claimed hybrids will not have the same morphological and physiological characteristics as I026458. I026458 can be crossed with any other inbred corn plant to produce the claimed hybrids. The claimed hybrids then will express a combination of

morphological and physiological characteristics that are different from each other, and which are also different from those expressed by I026458. That all hybrids will inherit half of their alleles from I026458 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids. The specification does not correlate any genes of I026458 with any of the traits that it expresses. Further, the claimed hybrids will inherit one allele for every gene from the other, unidentified and undescribed parent plant. The specification does not describe how those alleles inherited from I026458, or how the products of those alleles, will be affected by or interact with the alleles or their products inherited from the other parent. The expressed gene products will depend on the combination of the two alleles from each parent at each locus, whether the allele is dominant or recessive, and on the epigenetic effects of other genes. The fact that any hybrid plant will inherit half of its alleles from I026458 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants.

For example, if I026458 carries two recessive alleles for insect resistance, it will be susceptible to insects. If it is crossed to another inbred with a recessive allele at that locus, the hybrid will also be susceptible to insects. If the other chosen inbred has a dominant allele at that locus, the hybrid will be insect resistant, if simple Mendelian genetics governs the expression of this trait. Each inbred possesses thousands of genetic loci governing thousands of traits, including silk color, lodging resistance, leaf color, stalk color, disease resistance, stalk stiffness, waxy starch, days to maturity, etc., with a dominant or recessive allele at each locus. It is clear that the mere provision of one-half of the hybrid's genetic complement being inherited from

I026458 is woefully inadequate to describe the resultant hybrid, either genetically or morphologically.

Appellant also argues that the entire genetic contribution of corn plant I026458 is described by way of deposit of seed of I026458 with the ATCC, and believes that this represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishes them from other plants. In support, Appellant cites the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposit material (Appeal Brief, page 14, 1st full paragraph). However, in the patent considered in that decision, the deposited material corresponded exactly to one of the claimed products. The appeals court remanded the case for the district court to make findings on whether there was a correlation between the structure of the deposited material and the function of the variant material also claimed. Here, as in *Enzo*, the deposited inbred does not correspond exactly to the claimed hybrid. However, the functions of the claimed hybrid plants have not been correlated to the half of their genetic material originating from the deposited I026458 seed. The function of the plant grown from an I026458 seed is correlated with the structure of its entire genome, not just one half. The function of the claimed hybrid plants grown from the claimed hybrid seeds is correlated with the structures of their entire genomes, not just the alleles inherited from I026458. Further, half of the alleles of the hybrid are inherited from the other parent, and are not described by the deposited I026458 seed. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited I026458 seed, as discussed above.

Appellant continues, citing the decision of *The Regents of the University of California v. Eli Lilly and Co.*, for noting that a name alone does not satisfy written description if structural features commonly possessed by members of the genus are not defined. Appellant argues that here, all of the members of the claimed genus of hybrids having I026458 as one parent share the identical feature of having the genetic complement of I026458 (Appeal Brief, paragraph bridging pages 14-15). However, in *Eli Lilly*, the members of the genus shared a common function. In the instant application, the specification does not describe the function (i.e., morphological and physiological traits) of the claimed hybrids, and does not correlate the function of the hybrids with the structure of the genetic complement of I026458. Furthermore, the genetic complement of the other unknown parent has not been described, and hence Appellant has not provided a written description of the multitude of possible hybrid corn plants that would result from crossing the deposited inbred I026458 with any and all other inbred or hybrid corn plants.

Citing *Enzo Biochem, Inc. v. Gen-Probe Inc.* for support, Appellant argues that the Federal Circuit has held that a biological deposit may be used to satisfy written description for nucleic acids, whether the nucleic acid sequence is set forth in the specification or not. Appellant argues that in *Enzo*, the patent owner had deposited 6 bacterial strains and claimed nucleotide sequences hybridizing to the nucleic acids of these strains, although the patent application did not set forth the nucleic acid sequences of the strains. Appellant continues, arguing that in its holding, the Federal Circuit considered the burden placed on applicants were they required to sequence the genomes of the bacterial strains that were deposited in the patent considered in *Enzo*. Appellant argues that in the instant case, more effort would be required to sequence the more complex corn genome, and alleges that the Examiner is nonetheless requiring this of the

Appellant, in direct contradiction of *Enzo* (response, page 15, 1st full paragraph). However, the Examiner never made any such requirement. Further, sequencing of the bacterial genomes was not required to determine if the claims under consideration in *Enzo* met written description. Rather, the court noted that while the genomic DNAs of the deposited strains were not sequenced, that their accessibility to the public allowed one to conclude that the claimed nucleotide sequences were described by their ability to preferentially hybridize to the genomic DNA under defined, highly stringent hybridization conditions. The hybridizing nucleotide sequences also shared the same functional activity as the template sequences. Determination of the sequence of the genomic DNA of the deposited bacterial strains was not needed to determine if the claimed nucleotide sequences met written description. Here, the claims are directed to any and all hybrid seed and plants that are produced by crossing the deposited inbred corn plant (grown from I026458 seed) with any other corn plant. The claimed hybrid seeds and plants do not share the same functions (i.e., morphological and physiological traits) as those expressed by corn plants produced by growing the deposited I026458 seed, and share only 50% of the same DNA.

Appellant next argues that the Examiner attempted to counter (in the Office action mailed 23 September 2003, page 11, 1st full paragraph) the showing by Appellant (in the first Appeal Brief submitted 30 June 2003, page 10, 1st paragraph, and reiterated in the Appeal Brief submitted 23 December 2003, page 14, 1st paragraph) that the holding of *Enzo* establishes written description for the genome of corn variety I026458, by stating that *Enzo* is inapplicable because in that case a function was correlated to the deposited product (Appeal Brief, page 16, 1st full paragraph). However, this was not Appellant's previous argument. Rather, Appellant previously

argued that the deposit of seed of corn variety I026458 satisfied the written description requirement for the claimed hybrid seeds and plants of claims 24-26. The Examiner did not question the satisfaction of the written description requirement for seed of the corn variety I026458, but rather that of the claimed hybrid seeds and plants. Appellant now argues that the Examiner's response constitutes a misstatement of the holding of *Enzo* because 1) the alleged function in *Enzo*, the ability to hybridize to the deposited sequence, is a structural limitation and not a function, and 2) the question in *Enzo* was not whether a function had to be disclosed in order to have adequate written description for a claimed sequence, but whether a sequence could be claimed by way of function when it is described in the specification by way of deposit (response, page 16, 1st full paragraph). Appellant argues that the Federal Circuit stated that a deposit constitutes an adequate written description of deposited material sufficient to comply with the written description requirement, that the Federal Circuit did not condition this holding on a function that was disclosed. Appellant argues that therefore, there is no basis to conclude that the holding of *Enzo* does not demonstrate that Appellants have provided a written description of the entire genetic complement of corn seed of I026458 based on the ATCC deposit (Appeal Brief, paragraph bridging pages 16-17).

However, as discussed above, the Examiner did not previously indicate that the ATCC deposit of the I026458 seed failed to satisfy the written description requirement for that seed. Rather, the Examiner's response to Appellant's previous argument addressed why it was believed that the deposited seed did not describe the claimed hybrid seeds and plants. Further, while Appellant argues that the deposit of seed of I026458 satisfies the written description requirement for that seed, it is noted that not a single claimed hybrid seed has deposited.

Appellant argues that the claimed F1 hybrid plants having I026458 as one parent will share the same genetic complement from I026458, and are readily identifiable by the genetic marker analysis in Tables 6 and 8. Appellant argues that hybrid corn plant 7041221 has the SSR genetic marker profile of I026458 and includes the genetic markers from the second parent plant, and that this will be true for any other hybrid plant having I026458 as one parent, save for "an occasional difference at a locus due to spontaneous genetic rearrangements" (Appeal Brief, page 17, 1st full paragraph). However, while all of the claimed hybrids will inherit the SSR marker profile of I026458, they will not inherit the same genetic markers from the other parent as did hybrid 7041221, because they will have different parents, having different markers. The SSR marker profiles of the other parents are not described. Further, the description of corn plant 7041221 does not describe the morphological and physiological traits of all other corn plants that can be produced by crossing I026458 to any other corn plant. One skilled in the art cannot identify the morphological and physiological characteristics of corn plant 7041221 that will be expressed by all other members of the genus, nor can one identify the characteristics that will be different.

Further, while hybrid 7041221 has inherited the SSR marker profile of I026458, the specification does not describe the traits that are correlated with these markers. The traits expressed by 7041221 are not solely due to the presence of the alleles associated with the SSR markers inherited from the I026458 genome, or the genetic contribution of I026458, as discussed above. Further, written descriptions of each of the SSR and isozyme markers are not provided. The markers represent specific nucleotide sequences. While the markers are named, this is not

sufficient to describe the nucleotide sequences that they represent. Further, none of these markers have been linked to any expressed traits.

It is also noted that the specification does not describe the sequences of the primers that were used to produce this SSR profile. The specification indicates on page 61, lines 19-22, that the SSR analyses were conducted at Celera AgGen, and on page 64, at the bottom of Table 6, that primers used in the analyses are also from Celera AgGen. However, without a description of the sequences of the SSR markers, one cannot confirm the presence of the same SSR markers in any plant.

Appellant continues, arguing that the second plant that is used to make the claimed hybrids is irrelevant, as any second plant capable of reproduction may be used to make the hybrid. Appellant argues that the claims cannot be said to lack written description for the second genetic complement, particularly given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art. Appellant argues that any of the U.S. patents issued on hundreds of different corn plants could be used to produce an F1 hybrid plant having I026458 as one parent, and each of these would share the genetic complement of I026458 (Appeal Brief, paragraph bridging pages 17-18 and page 18, 1st full paragraph).

However, again, it is the interaction of the products of all of the alleles of the claimed hybrids, not just the products of the alleles inherited from I026458, which determine the traits of the claimed hybrids. Each parent contributes one set of chromosomes to the hybrid progeny, and each set of chromosomes comprises one allele for each gene at every locus in the genome, wherein alleles are alternate forms of the same gene that occur at a given locus. A phenotypic trait of the plant results from the expression of the two sets of alleles. The resulting phenotype of

the plant depends on how each allelic product interacts with the corresponding allelic product inherited from the other genome, as well as how each gene product interacts with other gene products in the genome. Some alleles of the same gene are dominant to others. The interaction of nonallelic genes by epistasis also affects the phenotype, and the combined effects of multiple genes determine quantitative traits. Given that a claimed hybrid corn plant comprises a set of alleles inherited from each parent and these two sets of alleles interact in a variety of ways to determine the hybrid's morphological and physiological traits, one cannot correlate the alleles inherited from I026458 alone, with the phenotype of the hybrid progeny. Thus, the deposit of I026458 seeds and the recitation of some phenotypic characteristics of corn plant I026458 is not sufficient to provide an adequate written description of all hybrid progeny that may be produced by crossing I026458 with a second, distinct corn plant. Appellant would have one believe that only half of a genome is sufficient to describe a plant. Yet, if only half of the genome of I026458 was deposited, it would not have been enough to describe its full genome, as discussed above.

Appellant then returns to the genetic marker data, alleging that the Action (presumed to be the Office action mailed 23 September 2003) attempts to downplay the significance of the genetic marker data in the specification, that no effort was made to show that any substantial number of marker loci actually are shared by other plants (Appeal Brief, paragraph bridging pages 18-19). However, it remains that if other corn plants possess the SSR markers named in Table 6, then this criterion cannot be used to distinguish the claimed plants from unrelated corn plants. Appellant argues that these "other" plants are not claimed, so this is irrelevant to written description (Appeal Brief, paragraph bridging pages 18-19). However, Appellant is arguing that

these SSR markers can identify the half of the hybrid's genome that was inherited from I026458. If other, unrelated corn plants also possess these markers, then this criterion does not distinguish the claimed hybrid seeds and plants from unrelated corn plants. Also, the specification does not mention anything concerning the traits expressed by the other corn plants named in Table 6, and how similar those traits are to the combination of traits expressed by I026458. Is a comparison to only two inbreds sufficient to establish that the sets of SSR and isozyme markers in Tables 6 and 8 can distinguish a corn plant as having I026458 as a parent from those that do not? Further, the specification fails to correlate any function, or trait, expressed by I026458, or the claimed hybrids, with any of the markers.

Appellant argues, regarding the availability of genetic markers or the primers used to detect the markers, that the service used to detect SSR markers is commercially available to the public, that SSR and other genetic marker systems that are well known may potentially be used, as described in the specification on pages 60-61 (Appeal Brief, paragraph bridging pages 18-19). However, that the service used to detect SSR markers is currently commercially available is not a guarantee that it will remain so for the life of a patent issuing from the application. Further, the specification at pages 60-61 only provides a general discussion of other types of genetic markers, and does not describe any actual markers possessed by corn plant I026458.

Appellant next argues, in response to the Examiner's previous arguments that the morphological and physiological characteristics of the hybrids have not been described, and that the manner in which the genes inherited by the hybrids would be expressed or interact has not been shown, that the Examiner's position misses the point that Appellant has gone one step

further by describing the claimed hybrid plants at the genetic level. Appellant asserts that a better description could not be made than at the genetic level (Appeal Brief, page 19, 1st full paragraph). However, again, Appellant is attempting to describe the claimed hybrids by only half of their genome. Appellant has deposited I026458 seed and, by extension, the I026458 genome, since the cells of the I026458 seed contain the I026458 genome. The claimed hybrids inherit only half of this genome, and the claimed hybrids do not have all of the same functions as those possessed by I026458. Given the genetic composition at each locus of the second inbred chosen as the hybrid's parent, the resultant hybrid may even have less than one-half of the traits exhibited by I026458.

The specification also provides the loci of many SSR and isozyme markers in the genome of I026458. However, as discussed above, the specification does not correlate any function of the claimed hybrids with this genetic information. The specification does not correlate any traits with any genes or molecular markers of I026458, and therefore the claimed hybrids. Further, while I026458 seed has been deposited, none of the hybrid seeds, which produce plants having traits and functions that are different from I026458, have been deposited.

Appellant continues, arguing that the law makes no distinctions regarding the manner in which applicant chooses to describe claimed compositions (Appeal Brief, page 19, 2nd full paragraph). However, the Examiner has not limited Appellant to describing the claimed invention in any specific manner. Appellant argues that the genetic complement of parent plant I026458 that will be comprised in the claimed hybrid plants has been described by way of the SSR and isozyme genetic marker profiles in Tables 6-9 (Appeal Brief, page 19, 2nd full

paragraph). However, as discussed above, while loci where these markers are located are identified, the sequences of the markers, or of primers used to locate them, are not described, nor are any functions of any alleles that may be associated with the markers described.

Appellants repeats the argument that a further description of the claimed hybrid plants is provided in the specification by way of hybrid 7041221, and believes that this plant is representative of all hybrids produced using I026458 as one parent, each of which comprise the genetic complement of the parent corn plant (Appeal Brief, page 20, 1st full paragraph). Appellant argues that Table 4 provides performance comparisons of 7041221 with other hybrid varieties (Appeal Brief, page 20, 1st full paragraph). However, all of the claimed hybrid plants would not have the same performance characteristics as 7041221. Appellant argues that the information of Table 4 combined with the morphological traits in Table 5, the SSR and isozyme marker profiles in Tables 8 and 9, and the description of I026458 and the shared structure among the hybrids is more than adequate to describe the claimed subject matter (Appeal Brief, page 20, 1st full paragraph). However, again, hybrids that do not share both of the same parents will not have the same combination of traits. The morphological traits in Table 5 and the performance of hybrid 7041221 cannot be extended to any other hybrid plant, and are not representative of all hybrids produced using I026458 as one parent.

Regarding claims 27-30, drawn towards corn plant I026458 containing single locus conversions: Appellant appears to be arguing that the specification describes such plants, simply because the definition of "single locus converted plants" provided in the specification indicates that such plants possess essentially all of the desired morphological and physiological characteristics of plant I026458 in addition to the characteristics conferred by the single locus

transferred. Appellant argues that because the specification indicates that the claimed plants possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]", that they have more than adequately described such plants (Appeal Brief, paragraph bridging pages 20-21). However, the specification does not describe any and all single locus conversion traits, nor the source of all of said traits. The traits conferred by the single locus may also change one or more of the traits expressed by I026458, depending on what the locus encodes. A single locus whose product confers male sterility, for example, will change a trait of inbred corn plant I026458, rather than adding an additional trait. Further, the descriptions of plants that express "essentially" all of the "desired" characteristics of I026458 are not described. The definition indicates that the plants possess the "desired" characteristics of I026458. The "desired," as opposed to the "undesired," traits are not described. Further, page 31 of the specification indicates that the goal of a backcross procedure is to alter or substitute a single trait in the original inbred, and that this is accomplished by modifying or substituting a single locus in the inbred with the desired locus in the other plant, while retaining essentially all of the rest of the morphological and physiological constitution of the original inbred (lines 4-8). The claimed plants therefore may not still possess the combination of traits expressed by I026458, in addition to the trait conferred by the introduced locus.

Appellant cites *In re Gosteli* for indicating that the written description requirement does not require an applicant to describe exactly the subject matter claimed, but that the description must clearly allow persons of ordinary skill in the art to recognize what is claimed (Appeal Brief, paragraph bridging pages 20-21). However, the specification does not describe the traits expressed by all of the claimed plants, nor what set of traits are present in all of the claimed

plants to allow persons of ordinary skill in the art to recognize the claimed plants. The claimed genus reads on a multitude of I026458 plants further comprising a single locus conversion, and having a multitude of different morphological and/or physiological traits. As discussed, the specification does not describe plants that express only some or "desired" traits that are expressed by I026458, or how to distinguish such plants from I026458. Further, single loci, for example those encoding a transcription factor, may affect one or more traits expressed by I026458. The claimed plant then may not express all of the "desired" traits of I026458. Such plants are not described by the specification.

In response to the issue raised in the previous Office actions that the claimed plants encompass introducing genes, or single loci, that have yet to be discovered, Appellant argues that undiscovered genes are not claimed, and that the fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant, because it is the single locus conversion of corn plant I026458 that is claimed (Appeal Brief, paragraph bridging pages 21-22). However, if a gene has not been discovered or isolated at the time the instant application was filed, Appellant cannot be in possession of a corn plant into which this gene was deliberately introduced. Furthermore, at least claim 30 explicitly recites undiscovered genes, since single loci that alone govern "yield enhancement" or "enhanced yield stability" have not been discovered.

Appellant continues, arguing that under the Examiner's reasoning, any claim could be read to encompass subject matter yet to be invented and therefore not described. For example, a corn plant transformed with a *Bacillus thuringiensis* gene would be invalid because it would encompass corn varieties yet to be discovered (Appeal Brief, paragraph bridging pages 20-21). In this example, however, there is only one genetic structure that is relevant, that of the *B.*

thuringiensis gene, and only one function, that conferred by the product of the gene. A claim drawn towards a corn plant containing the gene may be described, if the structure and function of the gene is described. In the instant application, the invention encompasses corn seed I026458 and the plant produced by it. The deposit of the seed satisfies the written description requirement for the I026458 seed. A single locus that is substituted for another, or the introduction of another locus into I026458, would amend the structure and functions of corn plant I026458.

Appellant argues that the Examiner supposedly ignored evidence submitted in a prior response that the specification recites numerous single locus traits with a publication reference or patent number. Appellant goes on to provide several examples (Appeal Brief, page 22 1st full paragraph to page 24, 1st full paragraph). However, this argument was rebutted on pages 7-8 of the Office action mailed 23 January 2003 and in the Office action mailed 23 September 2003, page 16. While the specification does cite references that describe numerous isolated genes, not all of the cited references actually teach that genes discussed therein have been discovered or isolated. For example, the references cited in the specification do not describe isolated single genes or loci that confer yield enhancement or yield stability. If such single loci have not been discovered or isolated, Appellant cannot be in possession of I026458 plants comprising this single locus conversion. The claims broadly encompasses plant I026458 further comprising any single locus conversion, controlling any trait, including loci that have yet to be identified as independently controlling a trait. Appellant cannot be in possession of plants further comprising single loci that have yet to be identified. It is also noted that the Examiner is not asking Appellant to identify each and every gene known to man by name, but to identify the types of

single loci, that alone control a trait, that have been isolated in the prior art. For example, many genes or single loci were known in the prior art that confer disease resistance, or herbicide resistance. In the Office action mailed 23 January 2003 and 23 September 2003, it was suggested that the claims be amended to recite the types of single loci, not individual or specific loci names. Further, it is unclear how the introduction of a multitude of non-exemplified transgenes, encoding a multitude of proteins or enzymes or inhibitory RNA products which would be involved in a multitude of metabolic pathways resulting in a multitude of traits, would interfere with one or more of the traits expressed by corn plant I026458. Such interference would result in the production of a multitude of corn plants with a different collection of traits than the exemplified inbred.

Appellant argues that techniques for introducing single locus traits by genetic transformation were well known (Appeal Brief, paragraph bridging pages 24-25). That methods to produce genetically transformed corn plants existed at the time of the invention is, of course, not disputed. However, methods for producing a product do not describe the product itself. See *Bayer v. Housey*, Appeal No. 02-1598, (Fed. Cir. 2003), decided 22 August 2003, penultimate page: "processes of identification and generation of data are not steps in the manufacture of a final [drug] product".

Proposed claim amendments that address the subject matter of instant claims 27-30, which were previously discussed with Appellant but not accepted, are presented in Appendix A at the end of this Examiner's Answer. A discussion of why these proposed claims are deemed acceptable is also provided below.

Regarding claim 31: Appellant argues that the claim is a process claim that involves crossing corn variety I026458 according to the specified steps. Appellant indicates that it appears to be the position of the Examiner that written description must be provided for each intermediate product claimed as a composition of matter. Appellant submits that this is a misstatement of the law and that this rejection has not been set forth on the record, and that no basis in law or fact has been given for maintaining the rejection (Appeal Brief, paragraph bridging pages 24-25). However, this rejection has been set forth in previous Office actions, and the basis for the rejection was given in the Office action mailed 23 September 2003, citing 64 Fed. Reg. 71427, 71428 (1999), comment No. 4. In fact, in the Appeal Brief, paragraph bridging pages 26-27, Appellant acknowledges that this citation was made.

Appellant argues that all that the comment says is that the Written Description Guidelines will address process and product-by-process, claims, e.g., this will be done in the future (Appeal Brief, paragraph bridging pages 26-27). However, the comment does not indicate that this will be done in the future. On the contrary, the comment states that the "suggestion to address process and product-by-process claims has been adopted."

Appellant argues that the Examiner failed to cite the actual Guidelines themselves. Appellant directs attention to the Guidelines (Fed. Reg. Vol. 66, page 1106) where it is indicated that the analysis of written description involved determining whether the application describes the complete structure or acts of a process of the claimed invention as a whole, and that if the application does not disclose the complete structure or acts of a process, to determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention. Appellant argues that theses sections demonstrate that the Guidelines

distinguish product and process claims, and that the Examiner failed to apply the Guidelines (Appeal Brief, page 27, 1st full paragraph). However, the patentability of the method of claim 31 does not lie in the acts of the process, which are the simple acts of crossing corn plants, allowing progeny seed to be produced, and growing progeny plants from the seed, but rather in the compositions used in the method. The method of claim 31 includes steps in which undescribed hybrids (produced by crossing inbred corn plant I026458 with a second, different corn plant) are crossed with other corn plants. Comment No. 4 of 64 Fed. Reg. 71427, 71428 (1999) indicates that the suggestion to address process and product-by-process claims, to distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those where the patentability rests in the steps of the process itself, has been adopted. Accordingly, claim 31 does not meet the written description requirement, since the method requires hybrid corn plants that are not described for the reasons discussed above.

Appellant continues, arguing that what is required to meet written description is that an Applicant show that he/she was in possession of the claimed invention. Appellant argues that here a process is claimed, not a product of a process, and thus the steps of the process, not intermediate or final products, must be described (Appeal Brief, page 28, 1st full paragraph). However, as discussed above, the suggestion that written description of process claims in which patentability depends on the compositions used in them, as opposed to those where patentability rests in the method steps, has been adopted into the Guidelines. Appellant cites *Vas-Cath, Inc. v. Mahurkar* in support of the argument that all that needs to be shown is that the Applicant is in possession of the claimed invention (Appeal Brief, page 28, 1st full paragraph). However, for the reasons discussed above regarding hybrids produced by crossing corn plant I026458 with a

different corn plant, Appellant is not in possession of progeny plants produced in steps (a)-(d) of claim 31. Also note that steps (c)-(d) of claim 31 requires possession of plants beyond the F1 generation of plants, and that steps (b)-(d) indicate that progeny plants of any generation can be crossed with itself or a second plant. Because Appellant is not in possession of such plants, Appellant is likewise not in possession of the methods of crossing the plants.

Appellant argues that corn breeding is well known to those of skill in the art, that without it there would not be commercial corn varieties (Appeal Brief, page 29, 1st full paragraph). However, it is not in dispute that corn breeding is well known. Appellant argues that all of the steps of claim 31 are typical of the process used for the production of new corn varieties, save for the novelty of corn variety I026458 (Appeal Brief, page 29, 1st full paragraph). The Examiner disagrees, and maintains that the progeny plants of steps (b)-(d) also need to be described, as written description of this process claim depends on compositions used in it, and not in the steps (the simple acts of conducting crosses and growing plants) of the process themselves.

Claims 27-30 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards inbred corn plant I026458 further defined as having a genome comprising any single locus conversion, encoding any trait; or wherein the single locus was stably inserted into a corn genome by transformation.

The specification teaches that single locus converted plants are produced by crossing a first inbred of interest with another "donor" inbred parent plant, which contains the single locus that is to be introduced into the first inbred. The progeny of that cross is then backcrossed with the first inbred. The progeny of the backcross gets backcrossed with the first inbred several more times, until a plant is recovered that has essentially all of the desired morphological and physiological traits of the original, first inbred, in addition to the trait expressed by the single locus transferred from the donor inbred plant (paragraph bridging pages 30-31). The specification at pages 35-36 provides a summary of the crosses performed to introduce a locus encoding cytoplasmic male sterility into a DEKALB proprietary inbred corn plant, designated "85DGD1." The specification does not teach any I026458 plants comprising a single locus conversion produced by crossing.

A review of claim 27 indicates that it encompasses corn plant I026458, and therefore all of its morphological and physiological traits, and further comprising any single locus in its genome. The practice of crossing two plant varieties, each expressing two different desired traits, for example, to obtain a single variety that expresses both desired traits, is well established. The specification, however, does not teach any I026458 plants comprising a single locus conversion produced by backcrossing, wherein the resultant plant retains all of its morphological and physiological traits in addition to exhibiting the single trait conferred by the introduced single locus. It is not clear that single loci may be introduced into the genetic

background of a plant through traditional breeding, while otherwise maintaining the genetic and morphological fidelity of the original inbred variety. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single locus conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single locus conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of backcross conversions taught in the prior art, in order to yield the claimed

plants which differ from I026458 only in comprising a single locus conversion and by the expression of a single trait.

The specification also teaches that single loci may be introduced into a corn plant by transformation, and that methods for genetic transformation of corn were known in the prior art (page 33, lines 12-21). Claim 28 recites the recitation, "wherein the single locus was stably inserted into a corn genome by transformation" (emphasis added). This recitation does not clearly indicate that it was plant I026458 that was transformed, and the claim encompasses the embodiment that another corn plant can be transformed, wherein the single locus would be introduced into I026458 by crossing.

The specification does not enable the introduction of all types of transgenes (comprising single loci) into corn plants. As broadly interpreted, the claims encompass I026458 plants comprising any type of single locus, including those that have not been isolated at the time the application was filed, and encoding any trait. The prior art shows that hundreds of nucleotide sequences encoding products that confer various types of plant traits have been isolated at the time the instant invention was filed. One skilled in the art can transform any of these isolated nucleotide sequences known in the prior art into a corn plant cell, and regenerate a transgenic plant from the transformed cell. However, the claims do not place any limit on the single locus to be introduced. For example, isolated loci whose products confer yield enhancement or enhanced yield stability (recited in claim 30), were not known in the prior art. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). Undue experimentation would be

required by one skilled in the art to isolate single loci that govern the traits encompassed by the claims. Claims 27-29 also encompass plants with single loci whose functions are unknown. One skilled in the art would not know how to use plants containing such loci. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Furthermore, the effects of expression of the single locus on the traits expressed by I026458 are unknown. The specification does not teach one how to use the claimed plants if all of the morphological and physiological traits of I026458 are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Appellant's arguments and Examiner's response:

Regarding the aspect of the rejection concerning the enablement of corn plants of variety I026458 comprising a single locus conversion, Appellants argue that no basis has been given to show that these references have any relevance to corn plants. Appellant argues that there is no support for the Examiner's assertion that the cited references concerning petunias, sugar beets, and tomatoes would apply to corn, and that the Action attempts to require Appellant to show why this is not true. Appellant argues that it is the burden of the Office to support its rejections (Appeal Brief, paragraph bridging pages 29-30 and page 30, 2nd full paragraph).

However, the rejection was supported with cited references. The rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by

backcrossing, while recovering all of the original plant's genome. Linkage drag appears to be a phenomenon that occurs in all plant types. Examples are lacking in the prior art of plants in which linkage drag does not occur. There is no evidence that corn is exempt from this universal trend. Linkage drag, for reasons embellished in the previous Office action and repeated above, would prevent one skilled in the art from making the I026458 plants comprising single locus conversions as currently claimed.

Further, the single locus may encode any product having any function, and can therefore affect the other traits expressed by I026458. For example, if the single locus encodes a transcription factor, the expression of numerous genes may be affected, which in turn would affect the traits expressed by I026458. In such a scenario, one may not obtain a plant having all or even most of the desired morphological and physiological traits of I026458, in addition to the trait conferred by the single locus.

In order to produce a single locus converted plant, a first inbred of interest is crossed with another "donor" inbred parent plant, which contains the trait that is to be introduced into the first inbred. The progeny of that cross is then backcrossed with the first inbred. The progeny of the backcross gets backcrossed with the first inbred several more times, until a plant is recovered that has essentially all of the desired morphological and physiological traits of the original, first inbred in addition to the trait (single locus) transferred from the donor inbred parent (specification, paragraph bridging pages 30-31). The claims, however, broadly encompass plants that comprise exactly the genome of I026458, further comprising just a single additional locus. While the introduction of a desired trait from one plant into another using crossing techniques is well known in the prior art, what is not clear is that a plant that has exactly the same genome as

I026458 is recovered, in addition to the introduced single locus. The claims encompass such plants. The very first cross involves crossing I026458 to another plant and results in a plant that expresses traits that are very different from those expressed by I026458, due to the presence of the genetic material from the non-I026458 plant. It is not clear, despite repeated backcrossing with I026458, that a plant having the exact same genome of I026458 can be recovered (in addition to the introduced single locus), particularly in view of the genetic linkage of multiple genes conferring multiple additional traits, as established by the cited references. The specification attempts to address this by indicating that "essentially" all of the "desired" morphological and physiological traits of an inbred are recovered, in addition to the transferred single locus (page 30, lines 23-27). However, the claims are directed to exactly plant I026458 further comprising the single locus.

Appellant argues that the Examiner further disregarded the example of a conversion that was made with a proprietary corn variety by stating that information has been left out, such as the number of crosses that were performed at each step. Appellant argues that no such steps are left out (Appeal Brief, page 30, 1st full paragraph). However, the Examiner never made any such allegation that a number of crosses were left out. Rather, the rejection raised the issue that there is no indication that all of the morphological and physiological traits of the DEKALB proprietary inbred corn plant were recovered, and that only one single locus was transferred from the donor parent.

The rejection also raised the issue that claims 28-30 broadly encompass corn plants comprising any type of single loci, encoding any trait, including those that have not yet been identified or isolated. The claims are not enabled for plants comprising such unknown loci.

Appellant does not address this issue in the Appeal Brief. For example, single loci that alone confer the trait of yield enhancement or enhanced yield stability, recited in claim 30, are unknown. The Examiner would like to point out that he is not requiring Appellant to identify each and every single loci or transgene by name. It is suggested that claims 27-30 be amended to indicate the type of single locus, not any specific single locus by name, contemplated by the specification. For example, many herbicide resistance genes or plant disease resistance genes were known in the prior art. Claim 30 already does this, but the claim also recites traits that are not conferred by single loci. If the isolated gene (or single locus) is taught and known in the prior art, one skilled in the art would know how to make and use the claimed plant.

The Examiner would also like to note that prior to Appellant's submission of the Appeal Brief of 23 December 2003, Supervisory Patent Examiner Amy Nelson faxed to Appellant a proposed, generic set of claim amendments that, after being rewritten to be particularly drawn towards the instant invention, would place the application in condition for allowance. The proposed claims particularly address the subject matter of, and would replace, pending claims 16 and 27-30, which are drawn towards I026458 plants further comprising a nuclear or cytoplasmic gene conferring male sterility, or I026458 plants further comprising a single locus conversion, or wherein the single locus was stably inserted into a corn genome by transformation. However, a response to the offer was never received from the Appellant for this application. The proposed claim amendments, as they would apply to the instant application, are provided below in Appendix A. Regarding the proposed claims 32-41, directed towards methods comprising

transforming corn plant I026458 and plants produced by the methods: the methods are considered acceptable to the Examiner because they indicate the traits that would be affected by the transgene (a single locus), or it recites the type of transgene that is intended to be introduced into the plant. Of course, Appellant would not be limited to only those traits mentioned in the proposed claims. Any such trait may be recited, provided that there is written descriptive support in the specification and the prior art teaches that genes or single loci that affect such traits have been isolated. It is again noted that the Examiner is not requiring that the claims recite the actual names of any genes. Regarding the proposed claims 42-46, drawn toward a method of introducing a desired trait into the inbred plant of the invention using backcrossing techniques (which would result in plants comprising a single locus conversion, to use the terminology of the instant application), and the plants produced by the method: the proposed method claim is considered acceptable because it 1) indicates the types of traits that are contemplated, and 2) indicates that, after the inbred plant of the invention is crossed with a plant that contains the desired trait to be transferred, the progeny plant is to be backcrossed and selected at least four times, to ensure that undesirable genetic material from the donor plant is lost and that the resultant plant will also recover all of the traits of the original plant that are taught in Table 3 of the specification. It is important that the resultant plant retain the traits recited in Table 3, as it is this combination of traits that make inbred corn plant I026458 free of the prior art. Note that the proposed method claim does not require the recovery of I026458 traits that are absent from Table 3, and therefore does not require that the resultant plant express all of the morphological and physiological traits of corn plant I026458. The method of the

proposed claim results in a plant that expresses the traits of I026458 recited in Table 3, in addition to the introduced trait.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Appendix A- Proposed New Claims

32. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 5 with a nucleic acid molecule that confers male sterility.

33. A male sterile corn plant produced by the method of claim 32.

34. A method of producing an herbicide resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers herbicide resistance.

35. An herbicide resistant corn plant produced by the method of claim 34.

36. The corn plant of claim 35, wherein the transgene confers resistance to an herbicide selected from the group consisting of glyphosate, sulfonylurea, and phosphinothricin.

37. A method of producing an insect resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers insect resistance.

38. An insect resistant corn plant produced by the method of claim 37.

39. The corn plant of claim 38, wherein the transgene encodes a *Bacillus thuringiensis* endotoxin.

40. A method of producing a disease resistant corn plant comprising transforming the corn plant of claim 5 with a transgene that confers disease resistance.

41. A disease resistant corn plant produced by the method of claim 40.

42. A method of introducing a desired trait into corn inbred line I026458 comprising:

(a) crossing I026458 plants grown from I026458 seed, representative seed of which has been deposited under ATCC Accession No. PTA-3228, with plants of another corn line that comprise a desired trait to produce F1 progeny plants, wherein the desired trait is selected from the group consisting of male sterility, herbicide resistance, insect resistance, and disease resistance;

(b) selecting F1 progeny plants that have the desired trait to produce selected F1 progeny plants;

(c) crossing the selected progeny plants with the I026458 plants to produce backcross progeny plants;

(d) selecting for backcross progeny plants that have the desired trait and traits of corn inbred line I026458 listed in Table 3 to produce selected backcross progeny plants; and

(e) repeating steps (c) and (d) three or more times in succession to produce selected fourth or higher backcross progeny plants that comprise the desired trait and all of the traits of corn inbred line I026458 listed in Table 3 as determined at the 5% significance level when grown in the same environmental conditions.

43. A plant produced by the method of claim 42, wherein the plant has the desired trait and all of the traits of corn inbred line I026458 listed in Table 3 as determined at the 5% significance level when grown in the same environmental conditions.

44. The plant of claim 43 wherein the desired trait is herbicide resistance and the resistance is conferred to an herbicide selected from the group consisting of: sulfonylurea, glyphosate, and phosphinothricin.

45. The plant of claim 43 wherein the desired trait is insect resistance and the insect resistance is conferred by a transgene encoding a *Bacillus thuringiensis* endotoxin.

46. The plant of claim 43 wherein the desired trait is male sterility and the trait is conferred by a nucleic acid that confers male sterility.